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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,814	09/04/2002	Andrew Austen Mortlock	ASZD-P01-599	2356
28120	7590	12/02/2004	EXAMINER	
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			TRUONG, TAMTHOM NGO	
			ART UNIT	PAPER NUMBER

1624

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,814

Applicant(s)

MORTLOCK ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10, 12-14, 19, 20, 25, 27, 29, 30 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-7, 10, 12-14, 19, 20, 25, 27, 29, 30, 32-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment of 9-16-04 has been fully considered. The "Use claims" have been amended as "a method for treating colorectal and breast cancer...", and thus, the amended claims have obviated the previous rejection of 35 USC 101. The deletion of "prodrug" has also rendered moot the previous rejection of 35 USC 112, second paragraph. The insertion of matching parenthesis has overcome the "Claim Objections". Finally, the cancellation of claims 21-24 have overcome the previous 102 rejection.

Claims 8, 9, 11, 15-18, 21-24, 26, 28, and 31 are cancelled.

Claims 1-7, 10, 12-14, 19, 20, 25, 27, 29, 30, 32-40 are pending.

Due to the extensive list of substituents represented by X, R¹-R⁴, and R⁵ (or R⁶⁴), the following restriction is deemed necessary.

Lack of Unity

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-7, 10, 12-14, and 32 drawn to a method of treating colorectal or breast cancer using a compound of formula (I), classified in class 514, various subclasses depending on substituents. Further restriction will be required if this group is elected.

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Group 2, claim(s) 19, 20, 25, 27, 29, 30, and 33-40 (part of each) , drawn to compounds of formula IIA or IIC having the following substituents:

X is O;

R^1 , R^2 , R^3 , and R^4 – independently are **not** $R^{15}X^1$;

Z is C(O); R^{64} is optionally substituted hydrocarbyl;

Classified in class 544, various subclasses depending on substituents.

Group 3, claim(s) 19, 20, 25, 27, 29, 30, and 33-40 (part of each) , drawn to compounds of formula IIA or IIC having the following substituents:

X is O;

R^1 , R^2 , R^3 , and R^4 – independently are **not** $R^{15}X^1$;

Z is S(O)₂; R^{64} is optionally substituted hydrocarbyl;

Classified in class 544, various subclasses depending on substituents.

Group 4, claim(s) 19, 20, 25, 27, 29, 30, and 33-40 (part of each) , drawn to compounds of formula IIA or IIC having the following substituents:

X is S, S(O), or S(O)₂;

R^1 , R^2 , R^3 , and R^4 – independently are **not** $R^{15}X^1$;

Z is C(O); R^{64} is optionally substituted hydrocarbyl;

Classified in class 544, various subclasses depending on substituents.

Group 5, claim(s) 19, 20, 25, 27, 29, 30, and 33-40 (part of each) , drawn to compounds of formula IIA or IIC having the following substituents:

X is S, S(O), or S(O)₂;

R^1 , R^2 , R^3 , and R^4 – independently are **not** $R^{15}X^1$;

Z is S(O)₂; R^{64} is optionally substituted hydrocarbyl;

Classified in class 544, various subclasses depending on substituents.

Group 6, claim(s) 19, 20, 25, 27, 29, 30, and 33-40 (part of each) , drawn to compounds of formula IIA or IIC having the following substituents:

X is NR^{12} ;

R^1 , R^2 , R^3 , and R^4 – independently are **not** $R^{15}X^1$;

Z is C(O); R^{64} is optionally substituted hydrocarbyl;

Classified in class 544, various subclasses depending on substituents.

Group 7, claim(s) 19, 20, 25, 27, 29, 30, and 33-40 (part of each) , drawn to compounds of formula IIA or IIC having the following substituents:

X is NR^{12} ;

R^1 , R^2 , R^3 , and R^4 – independently are **not** $R^{15}X^1$;

Z is S(O)₂; R^{64} is optionally substituted hydrocarbyl;

Classified in class 544, various subclasses depending on substituents.

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Group 8, claim(s) 19, 20, 25, 27, 29, 30, and 33-40 (part of each) , drawn to compounds of formula IIA or IIC having the following substituents:

X is O;

R¹, R², R³, and R⁴ – independently are **not** R¹⁵X¹;

Z is C(O); R⁶⁴ is optionally substituted **heterocyclyl**;

Classified in class 544, various subclasses depending on substituents.

Group 9, claim(s) 19, 20, 25, 27, 29, 30, and 33-40 (part of each) , drawn to compounds of formula IIA or IIC having the following substituents:

X is O;

R¹, R², R³, and R⁴ – independently are **not** R¹⁵X¹;

Z is S(O)₂; R⁶⁴ is optionally substituted **heterocyclyl**;

Classified in class 544, various subclasses depending on substituents.

Group 10, claim(s) 19, 20, 25, 27, 29, 30, and 33-40 (part of each) , drawn to compounds of formula IIA or IIC having the following substituents:

X is S, S(O), or S(O)₂;

R¹, R², R³, and R⁴ – independently are **not** R¹⁵X¹;

Z is C(O); R⁶⁴ is optionally substituted **heterocyclyl**;

Classified in class 544, various subclasses depending on substituents.

Group 11, claim(s) 19, 20, 25, 27, 29, 30, and 33-40 (part of each) , drawn to compounds of formula IIA or IIC having the following substituents:

X is S, S(O), or S(O)₂;

R¹, R², R³, and R⁴ – independently are **not** R¹⁵X¹;

Z is S(O)₂; R⁶⁴ is optionally substituted **heterocyclyl**;

Classified in class 544, various subclasses depending on substituents.

Group 12, claim(s) 19, 20, 25, 27, 29, 30, and 33-40 (part of each) , drawn to compounds of formula IIA or IIC having the following substituents:

X is NR¹²;

R¹, R², R³, and R⁴ – independently are **not** R¹⁵X¹;

Z is C(O); R⁶⁴ is optionally substituted **heterocyclyl**;

Classified in class 544, various subclasses depending on substituents.

Group 13, claim(s) 19, 20, 25, 27, 29, 30, and 33-40 (part of each) , drawn to compounds of formula IIA or IIC having the following substituents:

X is NR¹²;

R¹, R², R³, and R⁴ – independently are **not** R¹⁵X¹;

Z is S(O)₂; R⁶⁴ is optionally substituted **heterocyclyl**;

Classified in class 544, various subclasses depending on substituents.

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Group 14, claim(s) 19, 20, 25, 27, 29, 30, and 33-40 (part of each) , drawn to compounds of formula IIA or IIC having the following substituents:

R^1 , R^2 , R^3 , and R^4 – independently are $R^{15}X^1$;

Classified in class 544, various subclasses depending on substituents. Further restriction will be required if this group is elected.

The inventions listed as Groups 1-11 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- a. The invention of group 1 is drawn to a method of use which requires an additional search. The inventions in group 2-14 are drawn to quinazoline compounds that are distinct by the substituents represented by X, R^1 - R^4 , and R^{64} .
- b. Although groups 2-14 share a special technical feature(s) of *quinazolyl* group, said special technical feature(s) does not define a contribution over the prior art, i.e., it can be anticipated by or obvious in view of the prior art. Furthermore, it is the combination of the *quinazolyl* ring with substituents represented by X, R^1 - R^4 , and R^{64} that gives the compounds of each group their distinct physical, chemical properties as well as biological activity.
- c. Under 35 U.S.C. 372(b)(2), “international applications designating but not originating in, the United States...the Commissioner may cause the question of unity of invention to be reexamined under section 121 of this title...” Thus, as discussed above, the instant invention clearly lacks unity according to PCT 13.2. Accordingly, restriction under 35 U.S.C. 121 and 372 is deemed necessary.

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Because these inventions are distinct for the reasons given above and the search require for one group is not required for other groups. Therefore, to search the 14 distinct inventions would indeed impose a serious burden upon the examiner in charge of this invention, restriction for examination purposes as indicated is proper.

Due to the complexity of the grouping, the restriction is presented in writing.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

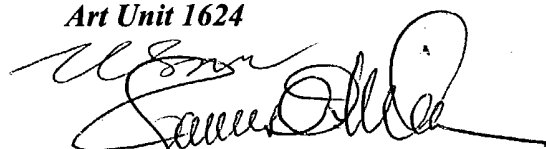
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (10:00-6:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tamthom N. Truong
Examiner
Art Unit 1624

11-21-04


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